

REMARKS

This Amendment is submitted with a Request for Continued Examination (RCE), and is in response to the Office Action mailed on September 29, 2005, in which all of the pending claims (6-15) were rejected under 35 U.S.C. § 103(a) as being unpatentable over JP 07-308310 (the '310 publication) in view of Slavin (USP 4,489,610), or alternatively over the '310 publication in view of Slavin, and further in view of RION AA-75 Audiometer Operation Manual. In addition, claims 1, 2, 4 and 12-14 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,416,482 and over claim 3 of U.S. Patent No. 5,811,681. Claims 1-5 and 12-14 were also provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 11/053,480, and those claims were identified as being in conflict with one another. These rejections were maintained because of an error that was made in the Terminal Disclaimer filed on August 9, 2005.

Background and Summary of the Claimed Invention

The present invention is directed to a system and method for evaluating the hearing ability of a test subject by delivering an audiometric test with automatic error correction. The test consists simply of a test subject putting on a pair of earphones and taking the audiometric test by signaling responses to test tones delivered to the earphones with a handswitch or a similar input apparatus. If the test subject makes an error in signaling responses with the handswitch, such as by pressing the handswitch when no test tones are present, pressing the handswitch multiple times for each tone, or failing to let go of the handswitch after pressing it, the error is automatically detected by a computer that is programmed to analyze the test subject's responses to determine the existence of an error condition. The computer then delivers audible corrective instructions that correspond to

the detected error condition to the test subject through the earphones, to instruct the test subject how to correct the error that was made. Finally, the computer automatically resumes the test by continuing to output test tones and receive responses from the test subject, without intervention by a test administrator or any other person. The manner in which the test is resumed is controlled by software, and takes into account the type of error condition that was detected so testing is resumed properly.

The system offered by the present invention was a significant improvement over previously existing test systems, in that it eliminated the necessity for a test examiner to administer the audiometric test. In prior systems, a test examiner supervised the administration of audiometric tests by providing instructions to the test subject before starting the test, monitoring the test subject's responses to test tones to ensure that no errors were made, and interrupting the test when the test subject made an error. This requirement of supervision by a test examiner limited the ability of prior systems to administer a large number of tests simultaneously (as a single test examiner could only monitor a limited number of simultaneous tests) and to provide corrective instructions in multiple languages (as this ability was limited to the languages spoken by the test examiner). In addition, the cost associated with employment of a test examiner could not be eliminated in prior systems.

Claim Rejections - 35 U.S.C. § 103

A. Claims 6-11 and 15 ('310 publication + Slavin)

Independent claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the '310 publication in view of Slavin.

Claim 6 recites a multimedia audiometer that includes:

- audio circuitry capable of generating test tones for delivery to earphones worn by a test subject;

- a computer selectively operable to produce instructions represented by sound waves for delivery to the earphones;
- microprocessor circuitry operatively coupled to the computer;
- an interface operatively coupled to the computer and the microprocessor circuitry for signaling whether the test subject perceives the audible test tones;
- a switch having a first state in which audible test tones generated by the audio circuitry are provided to the earphones, and a second state in which the instructions represented by sound waves produced by the computer are provided to the earphones; and
- software stored in at least one of the computer and the memory of the microprocessor circuitry for operating the system, detecting errors in the test subject's responses to test tones, selectively producing the instructions in response to the detected errors, and controlling the switch to switch to the second state when errors are detected in the test subject's responses and to automatically switch back to the first state following delivery of the instructions to the earphones so that testing is resumed without human intervention.

Independent claim 6 recites a switch having a first state in which audible test tones generated by the audio circuitry are provided to the earphones, and a second state in which the instructions represented by sound waves produced by the computer are provided to the earphones. Claim 6 also recites software that controls the switch to switch to a second state (in which instructions are provided to the test subject's earphones) when errors are detected in the test subject's responses to test tones. Thus, the system of claim 6 requires a computer-controlled switch that toggles back and forth between delivery of test tones and computer-generated instructions, without any human intervention.

In rejecting independent claim 6, the Examiner pointed to switch 6 of the '310 publication (FIG. 1) to satisfy the recitation of "a switch having a first state in which audible test tones generated by the audio circuitry are provided to the earphones...." The Examiner pointed out that "switch 6 has a first state in which audible test tones generated by the audio circuitry 4 are provided to the speakers 9, 10," and stated that "the primary difference between the claimed invention and the prior art consists in providing a second state in which instructions represented by sound waves are provided to the speakers 9, 10 when errors are detected in the test subject's responses and automatically switching back to the first state following delivery of the instructions so that testing is resumed."

To supply this deficiency in the teachings of the '310 publication (because switch 6 is not disclosed as having a second state for delivery of computer generated audible instructions), the Examiner pointed to other disclosure in the '310 publication, dealing with a situation where the test subject presses the response button when there is no examination sound. Specifically, paragraphs 62 and 63 of the '310 publication read as follows:

[0062] Further, if there is a response from patient regardless the examination sound has been turned off at step SP112, which means that the patient simply forgot to release the response button 24A or keeps pressing the response button 24A regardless he hears the examination sound or not, the CPU 3 at this moment prompts the patient to release hand from the response button 24A by presenting examination sound which is 10 [dB] greater than previous examination sound level in steps SP117-SP118 and turning off the examination sound at step SP119.

[0063] When the CPU 3 confirms that there has been no response from the patient at step 120, it judges that the reason why the patient kept pressing operation of the response button 24A was simply because he forgot to release

the response button 24A in step SP112, and the CPU 3 at this moment proceeds to step SP113 after reducing the examination level again by 10 [db] in step SP112.

Paragraphs 62 and 63 of the '310 publication describe a method in which the volume of a test tone is increased when pressing of the response button is detected after the previous test tone has been discontinued. This method does not control a switch (such as switch 6 shown in FIG. 1) to switch from providing test tones to providing computer generated audible instructions.

The Examiner contended that, based on the teaching of paragraphs 62 and 63, "the primary difference between the claimed invention and the prior art consists in providing audible instructions, rather than a prompt, to the test subject in order to prompt the test subject to release the response button." The Applicants respectfully submit that the '310 publication also does not disclose the structure or functionality of a switch that is operated under computer control to switch back and forth between the delivery of test tones and the delivery of computer generated audible instructions without human intervention. The importance of this difference will be explained in detail below.

To supply the teaching of providing audible instructions, the Examiner pointed to paragraphs 84 and 85 of the '310 publication, which read as follows:

[0084] (6) Other embodiment examples

Further, it is described in said embodiment example about a case wherein alarm 25 and display 26 are installed on examiner side to first inform examiner and then the examiner instructs patient to release response button 214A (sic), when patient keeps pressing response button 24A and patient operates response button 24A to press down by reacting to the masking noise, however, this invention is not restricted within this and for example,

it may be made to have display 26 on patient side and directly instruct patient to release the response button 24A with the display 26.

[0085] Further, it is described in said embodiment example about a case to notify that patient is keeping to press response button 24A and patient is operating response button to press down by reacting to masking noise, by using alarm 25 and display 26, however, the means of notification is not restricted within this and a lamp may be used which light when patient is keeping to press response button 24A or when patient is operating response button to press down by reacting to masking noise, or this may be notified with voice.

From the teachings of paragraphs 84 and 85, and in view of the teaching of presenting a louder test tone after detecting a response after an examination tone has been discontinued (paragraphs 62 and 63), the Examiner contended that "it would have been obvious to use vocal instructions, in lieu of visual instructions, in order to directly instruct the test subject to release the response button 24A and then to automatically continue testing if the subject releases the response button." The Examiner pointed to Slavin as teaching that the vocal instructions are produced by the computer.

To establish obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See M.P.E.P. 2143.

THERE IS NO SUGGESTION OR MOTIVATION TO MODIFY THE '310 PUBLICATION IN THE MANNER RECITED IN INDEPENDENT CLAIM 6

The '310 publication discloses two different routines for responding to a detection of an error (e.g., the patient pressing the response button after a test tone has been discontinued). The first routine is described in paragraphs 62 and 63, and involves simply the delivery of an additional test tone 10dB greater than the previously delivered tone. If the patient lets go of the response button in response to this additional tone, the CPU reduces the tone level by 10 dB and checks for a patient response to determine whether a threshold has been established. If the patient does not let go of the response button, the '310 publication describes the following routine:

[0064] On the contrary if the CPU confirms that there still is response from the patient at step SP112, it judges that the patient is pressing the response button 24A despite he is not hearing the examination sound, and move to step SP122 and displays a message saying "Patient response button has been pressed." on the display 26 and generate alarm sound from alarm 25 in following step SP123 to inform the examiner that the patient keeps pressing the response button despite the patient does not hear.

[0065] In following step SP 124, the CPU 3 wait for the restart button to be operated by being pushed down by the examiner, and when the restart button is operated to be pushed down, it clears the message on the display 26 and alarm sound of the alarm 25 in following step SP125, then moves to step SP126 to set the examination sound level at sufficiently low value again and proceeds to step SP102.

This routine is the second error handling routine disclosed in the '310 publication, in which test tones are interrupted and a notification (display and alarm) is

generated. In this routine, testing is only allowed to resume after a restart button is manually pressed by the examiner. Furthermore, this routine is disclosed as following the first routine (presentation of a +10 dB examination tone). The Applicants therefore disagree with the Examiner's contention that it would have been obvious to one skilled in the art to replace the first routine with the second routine, since the second routine was already implemented following the first routine. See Declaration of Roger C. Thede Under 37 C.F.R. 1.132, paragraphs 11 and 13. Replacing the first routine with the second routine would give a process that performs the second routine twice in succession, which is not suggested in any way in the '310 publication and for which no motivation or advantage exists. Thus, the requisite suggestion or motivation to modify the teachings of the '310 publication does not exist, and the rejection of independent claim 6 under 35 U.S.C. § 103 based on the combination of the '310 publication and Slavin should accordingly be withdrawn.

THE PROPOSED MODIFICATION TO THE '310 PUBLICATION WOULD STILL NOT DISCLOSE ALL OF THE ELEMENTS OF INDEPENDENT CLAIM 6

As was discussed above, the Examiner has contended that it would have been obvious to replace the first routine for dealing with a patient that presses the response button when no tone is present (presenting a +10 dB examination tone) with the second routine for dealing with errors (providing notification with a display/alarm) that is taught in the '310 publication. Even if this modification were made, the recited elements of independent claim 6 would not be satisfied.

Independent claim 6 recites a switch having a first state in which audible test tones generated by the audio circuitry are provided to the earphones, and a second state in which the instructions represented by sound waves produced by the computer are provided to the earphones. The only disclosure in the '310 publication for performing this

kind of switching is found in the description of the second routine for handling errors (see, e.g., paragraphs 64 and 65 reproduced above). When switching between test tones and a visual display/ alarm, the '310 publication teaches that resumption of testing can only occur after the examiner presses a restart button. Thus, modifying the '310 publication to replace the first error handling routine (which does not switch between test tones and a visual display/ alarm) with the second error handling routine (which does switch between test tones and the visual display/ alarm) will require the examiner to press the restart button in order to resume testing, because there is no teaching or suggestion in the '310 publication that switching from the visual display/ alarm (or a lamp, voice, or any other modification of the notification signal) back to test tones can be performed any other way. See Declaration of Roger C. Thede Under 37 C.F.R. 1.132, paragraphs 8, 10 and 12. This modified version of the '310 publication fails to disclose all of the elements of independent claim 6, which recites that software ... control[s] the switch to switch to the second state when errors are detected in the test subject's responses and to automatically switch back to the first state following delivery of the instructions to the earphones so that testing is resumed without human intervention. Because the proposed modification to the '310 publication (in combination with Slavin) fails to disclose all of the elements of independent claim 6, the rejection of claim 6 under 35 U.S.C. § 103 on this basis should be withdrawn.

The Examiner may contend that the proposed modification to the '310 publication is only to replace the presentation of a +10 dB examination tone (steps SP117-SP121, Figure 7) with a voice instruction/ alarm (steps SP122-SP123, Figure 7), so that testing could be automatically resumed. However, the Applicants respectfully submit that such a modification is not taught or suggested by the '310 publication. The presentation of a +10 dB examination tone does not involve any switching between test tones and instructions/ notification. This is why the '310 publication is able to resume testing if the patient lets go of the response button, because no switching from instructions/ notification

back to test tones is required. By contrast, in every instance in the '310 publication that interruption of test tones occurs, where the system switches from the delivery of test tones to notification of an error via a display and alarm, switching back to the delivery of test tones can only be accomplished after the examiner manually presses a restart button. See the '310 publication at paragraphs [0043], [0065] and [0075] and at Figure 4 (step SP45), Figure 7 (step SP124), and Figure 9 (step SP155). See Declaration of Roger C. Thede Under 37 C.F.R. 1.132, paragraphs 8-13. Thus, there is no teaching or suggestion in the '310 publication that delivery of instructions/notification can be followed by anything but a manual restart by the examiner.

Claims 7-11 and 15 depend from independent claim 6, and are allowable therewith.

B. Claims 6-11 and 15 ('310 publication + Slavin + RION manual)

Independent claim 6 was also rejected under 35 U.S.C. § 103(a) as being unpatentable over the '310 publication in view of Slavin and further in view of RION AA-75 Audiometer Operation Manual (RION).

In making this rejection, the Examiner contended that "RION teaches displaying an error message (paragraph 3 on page 131) and continuing with the audiometric examination (paragraph 5 on page 131). Accordingly, it would have been obvious in view of RION to automatically resume testing after directly instruct the test subject to release the response button 24A in the '310 publication."

The Applicant respectfully submits that the RION manual does not disclose displaying an error message and continuing with audiometric examination as suggested by the Examiner. Paragraph 3 states that "If there is abnormal response such as flapping the response button on and off, it displays "INCORRECT RESPONSE" on display monitor and interrupts the examination" (emphasis added). Paragraph 4 states that "If there is a normal response, it increases the sound by 10 dB and checks for continuous response."

Paragraph 5 then states that "If responses ceases it records that there was an abnormal response and repeats from (3) at a level that had a response."

The method disclosed in paragraphs 4 and 5 of the RION manual describe a "validation" type of logical testing procedure. If the test subject responds to a test tone ("If there is a normal response," paragraph 4), another tone is provided that is 10 dB louder than the previous tone to assure that the test subject pressed the response button as a result of hearing the previous tone, not by some fluke or accident. If the test subject responds to the louder (+10 dB) tone, the procedure continues to paragraph 7 ("If there is continuous response..."). If the test subject does not respond to the louder (+10 dB) tone, paragraph 5 states that "it records there was an abnormal response and repeats from (3) at a level that had a response." This procedure occurs to validate the response initially received from the test subject.

The overall error handling method disclosed in the RION manual corresponds exactly to the method taught in the '310 publication, with the "first routine" (involving a tone-based prompt) being described in paragraph 8. The routine described in paragraph 8 is the first routine of the '310 publication, described in paragraphs 62 and 63 and shown in Figure 7 as steps SP117-SP121. This routine involves increasing the level of a test tone by 10 dB if the response by the patient does not cease even after waiting 6 seconds. If the patient lets go of the response button, a temporary threshold value is determined and testing resumes. There is no switching from test tones to instructions/notification in this routine. See Declaration of Roger C. Thede Under 37 C.F.R. 1.132, paragraph 9.

The error handling described in paragraph 3 (and also in paragraphs 6 and 9) is the second routine of the '310 publication, described in paragraphs 64 and 65 (and also in paragraphs 43 and 75) and shown in Figure 4 (steps SP43-SP46), Figure 7 (steps SP122-SP125), and Figure 9 (steps SP153-SP156). This routine involves interruption of

examination, switching from the delivery of test tones to display of an error notification. The way that the system recovers from interruption of examination is described in paragraph 9, which states as follows:

If the examination is interrupted, please explain the patient how to respond once more, and resume the examination.

*For saving already measured data, please directly **press "START/STOP" button.***
*Fore (sic) redoing examination, please clear the data then **press "START/STOP" button.***

As disclosed in the RION manual, consistent with the '310 publication, a human examiner must always press a restart button to resume testing after testing has been interrupted by providing an error notification (display, alarm, etc.). See Declaration of Roger C. Thede Under 37 C.F.R. 1.132, paragraphs 8, 10 and 12. Thus, the RION manual also does not disclose, teach or suggest switching back to a first state (delivery of test tones) following delivery of instructions to the earphones so that testing is resumed without human intervention, as recited by independent claim 6. The rejection of claim 6 under 35 U.S.C. § 103 on this basis should accordingly be withdrawn.

Claims 7-11 and 15 depend from independent claim 6, and are allowable therewith.

C. Claims 12-14 ('310 publication + Slavin)

Independent claim 12 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the '310 publication in view of Slavin.

Claim 12 recites a computer adapted to perform an audiometric test of a subject that includes

- a test tone generator operable to deliver audible test tones to earphones worn by the subject
- an input/output interface, and

- software programmed to control the test tone generator to deliver the audible test tones to the earphones worn by the subject, monitor responses by the subject received over the input/output interface, detect errors in the subject's responses, selectively deliver audible corrective instructions to the earphones in response to the detected errors, and automatically resume delivery of the audible test tones after the audible corrective instructions are delivered without human intervention

As discussed above with respect to claim 6, the '310 publication (in combination with Slavin) does not disclose, teach or suggest a configuration in which the system delivers audible instructions in response to detection of an error condition and then automatically resumes testing by switching the output of the system back to delivering test tones. Moreover, there is no suggestion or motivation to modify the teachings of the '310 publication to provide this capability in the manner recited in claim 12. For the same reasons discussed above with respect to claim 6, the rejection of independent claim 12 under 35 U.S.C. § 103(a) should be withdrawn.

Claims 13 and 14 depend from amended independent claim 12, and are allowable therewith.

D. Claims 12-14 ('310 publication + Slavin + RION manual)

Independent claim 12 was also rejected under 35 U.S.C. § 103(a) as being unpatentable over the '310 publication in view of Slavin, and in further view of the RION manual.

As discussed above with respect to claim 6, the RION manual discloses essentially the same error handling routines as are disclosed in the '310 publication, and neither reference (in combination with Slavin) discloses, teaches or suggests a configuration in which the system delivers audible instructions in response to detection of an error

condition and then automatically resumes testing by switching the output of the system back to delivering test tones. Moreover, there is no suggestion or motivation to modify the teachings of the RION manual or the '310 publication to provide this capability in the manner recited in claim 12. For the same reasons discussed above with respect to claim 6, the rejection of independent claim 12 under 35 U.S.C. § 103(a) should be withdrawn.

Claims 13 and 14 depend from amended independent claim 12, and are allowable therewith.

Claim Rejections - Double Patenting

The Examiner did not accept the previously filed Terminal Disclaimer because the document referred to an incorrect application number. With this Amendment, a new Terminal Disclaimer is submitted to overcome the rejection of claims under the judicially created doctrine of obviousness-type double patenting.

New Claims

With this Amendment, new claims 16-21 are submitted for consideration and allowance. These claims had previously been presented in U.S. Application No. 11/053,408, and are directed to a method of performing an audiometric test of a subject. It is respectfully submitted that new claims 16-21 are allowable over the prior art of record for similar reasons to those discussed above with respect to independent claims 6 and 12, in that new independent claim 16 recites "automatically producing selected audible corrective instructions in response to ... detected errors and switching an input to the headset to the audible corrective instructions" and "automatically switching the input to the headset back to ... audible test tones after the audible corrective instructions are produced." Consideration and allowance of new claims 16-21 are respectfully requested.


CONCLUSION

In view of the foregoing, all of the pending claims (6-21) are in condition for allowance. A notice to that effect is respectfully requested.

Respectfully submitted,

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